

JAN 24 1997

K96 5063

**Summary of Safety and Effectiveness**

**Device Name:** Audiotone A-552 BTE

**Device Type:** BTE Hearing Aid

**Classification:** Air Conduction Hearing Aid (77ESD), Class I.

**Intended Use:** To amplify and transmit sound to the ear.

**Substantially  
Equivalent to:** Audiotone model A-52S which was cleared for distribution under document control number K901745.

**Registration  
Number:** 2110592

**Materials:** The hearing aid cases will be manufactured from materials that are commonly used in the industry.

**Technical  
Characteristics:** Dahlberg utilizes the ANSI S3.22-1987 methodology to test and obtain performance data for hearing aids.

**Fit:** Mild to severe as dictated by the individual users audiogram.

**Power:** Zinc-Air size 13 battery.